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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,428	12/18/2001	Stephen Griffin	1001.1545101	6502

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,428

Applicant(s)

GRIFFIN ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-29 and 32-39 is/are rejected.
- 7) ☒ Claim(s) 14, 15, 30 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 5/15/02 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 – 9, 16 – 25, 32 – 35, 37 – 39 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,662,621 to Lafontaine.

In reference to claims 1 – 9, 16 – 25 and 32, Lafontaine discloses applicant's claimed invention including: a guide wire shaft (24) having a proximal portion and a distal portion; a tubular polymeric member (26) comprising a shape memory polymer disposed on the distal portion of the shaft (Col. 5, lines 24 – 27; Col. 5, lines 46 – 53), the polymeric member having a first flexibility at a first temperature and a second flexibility at a second temperature, wherein the first temperature is less than the second temperature and the first flexibility is less than the second flexibility (Col. 5, lines 54 – 59); and a heat source on the distal portion of the shaft (Col. 6, lines 3 – 13), the heat source being in thermal communication with the polymeric member, where activation of the heat source causes the polymeric member to rise from the first temperature to the second temperature thereby changing the flexibility of the distal portion of the guide wire in that the shape of the polymeric member defines the path for the guide wire (Col. 5, line 46 – Col. 6, line 2). The first

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temperature is below the glass transition temperature and the second temperature is above the glass transition temperature (Col. 5, lines 54 – 59). The distal portion of the shaft has a tip portion including a coiled wire resistive heating element (Col. 6, lines 7 – 9).

In reference to claims 33 – 39, Lafontaine discloses a method of using a variable stiffness guide wire including: providing a guide wire including a distal portion (Col. 7, lines 8 – 12), a distal polymeric member having a glass transition temperature, and a heat source comprising a resistive heating element in thermal communication with the polymeric member; and changing the flexibility of the distal portion of the guide wire by activating or deactivating the heat source by supplying or removing electrical energy to the heating element and heating the polymeric member above the glass transition temperature (Col. 7, lines 13 – 23). Activating the heat source increases the flexibility of the distal portion of the guide wire while deactivating the heat source decreases the flexibility of the distal portion. The guide wire is navigated through the patient's vasculature (Col. 7, lines 8 – 12).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 10 – 13 and 26 – 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,662,621 to Lafontaine in view of U.S. Patent No. 5,531,685 to Hemmer et al.

In reference to claims 10 – 13 and 26 – 29, Lafontaine discloses the polymeric tube being disposed on the coiled wire (Figure 1; Col. 5, line 46 – Col. 6, line 9), a core wire extending through a tip portion (Figures 5 and 6) and the coiled wire being electrically coupled to the control unit (Col.

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6, lines 22 – 26). However, Lafontaine fails to disclose this electrical coupling being one or more lead wires. Hemmer et al. teaches the use of lead wires to electrically couple a heating element to a control unit (Col. 5, lines 3 – 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Hemmer et al., to use one or more lead wires to electrically couple the coiled wire to the control unit.

Response to Arguments

5. Applicant's arguments filed 8/21/03 have been fully considered but they are not persuasive. Applicant has asserted that a change in shape of a guide wire as disclosed by Lafontaine does not equate to a change in the flexibility of the guide wire. However, as can be seen in Col. 5, lines 54 – 59, the guide wire as disclosed by Lafontaine can be heated to change the flexibility of the guide wire (i.e. softened, easily deflectable).

Allowable Subject Matter

6. Claims 14, 15, 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF

November 2, 2003



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700